DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 29, 2016

NeoMed, Inc.
Melinda Harrison Smith, RAC, ASQ-CBA
Director, Quality and Regulatory Affairs
100 Londonderry Court, Suite 112
Woodstock, GA 30188

Re: K143344
Trade/Device Name: NeoMed NeoConnect™ Enteral Syringes with ENFit Connector
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PNR
Dated: March 11, 2015
Received: March 13, 2015

Dear Melinda Harrison Smith,

This letter corrects our substantially equivalent letter of April 7, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For Division

Douglas Silverstein -S
2016.09.29 08:04:39
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Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143344

Device Name
NeoMed NeoConnect™ Enteral Syringes with ENFit Connector

Indications for Use *(Describe)*
The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

NeoMed, Inc.
100 Londonderry Court
Suite 112
Woodstock, GA 30188
Tel: 770-516-2225
Fax: 770-516-2448

Contact: Melinda Harrison Smith, RAC, CBA
mharrison@neomedinc.com

Date Prepared: 18 November 2014

Establishment Registration Number: 3006520777

II. DEVICE

Trade Name:	NeoConnect™ Enteral Syringes
Common Name:	Enteral Syringe
Classification Name:	Gastrointestinal tube and accessories (21 CFR § 876.5980)
Regulatory Class:	II
Product Code :	PIF

III. PREDICATE DEVICE

NeoMed Oral / Enteral Syringe (0.5ml to 100ml) (K122373)

This predicate had not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The NeoMed NeoConnect™ Enteral Syringes are standard piston style syringes consisting of a syringe barrel with integral ENFit syringe tip, syringe plunger, syringe gasket, and supplied with a syringe tip cap. They are provided in varying sizes ranging from 0.5ml to 100ml nominal capacity. The integral syringe tip is a female ENFit connector which is compatible only with feeding tubes and extension sets that have ENFit male connectors to form a dedicated system that prevents wrong-route administration of fluids. They possess translucent barrels to provide visualization of fluid contents and volume.

V. INDICATIONS FOR USE

The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Indications for Use / Intended Use Statement	The device is indicated for use as a dispenser, a measuring device and an oral fluid transfer device. It is used to inject fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.	The device is indicated for use as a dispenser, a measuring device and a fluid transfer device. It is used to deliver fluids into the body via extension sets and feeding tubes in neonatal and small pediatric patients.
Patient Population / Environment of Use	Neonates and Small Pediatrics/ Hospital, Disposable and for single patient use only	Neonates and Small Pediatrics/ Hospital, Disposable and for single patient use only
Description of Device	An oral / enteral syringe consisting of a syringe barrel with integral tip (**tapered**), plunger, gasket, barrel lubricant and supplied with a syringe tip cap.	An enteral syringe consisting of a syringe barrel with integral tip (**ENFit**), plunger, gasket, barrel lubricant and supplied with a syringe tip cap.
Syringe Type	Oral / Enteral Syringe	Enteral Syringe
Principle of Operation	Piston Style Syringe	Piston Style Syringe
Syringe Tip Type	**Tapered**	**ENFit** (Dimensional compliance to AAMI/CN3:2014 (PS) Part 3 Table B.2 Female Enteral Small-Bore Connector).
Syringe Sizes (nominal volumes)	0.5ml to 100ml sizes	0.5ml to 100ml sizes
Syringe Barrel with integral syringe tip and volume graduations	Barrel – Polypropylene, class VI Graduation Ink – Orange	Barrel – Polypropylene, class VI Graduation Ink – Orange or Purple
Integral Syringe Tip Flexural Modulus	9500 Kg/cm^2 (932 MPa)	9500 Kg/cm^2 (932 MPa)
Syringe Plunger	Inert Polypropylene, class VI White Colorant	Inert Polypropylene, class VI White Colorant
Syringe Gasket	Silicone, Class VI, Black Colorant	Silicone, class VI, Black Colorant
Syringe Tip Cap	Inert Polypropylene, class VI Orange Colorant	Inert Polypropylene, class VI Orange or Purple Colorant
Barrel Lubricant	Polydimethylsiloxane class VI	Polydimethylsiloxane class VI
Packaging Material	Tyvek or medical grade paper / film primary pouch, Double Flute paper corrugate case box	Tyvek or medical grade paper / film primary pouch, Double Flute paper corrugate case box
Sterilization Method, SAL	Ethylene Oxide (EO), 10^{-6} SAL	Ethylene Oxide (EO), 10^{-6} SAL
Human Factors and Usability	Design Validation	Design Validation Device Master File #MAF2258
Risk Analysis	Device Risk Assessment including Design and User FMEA	Device Risk Assessment including Design and User FMEA Device Master File #MAF2258

VII. PERFORMACE DATA (BENCH)

The following performance testing was conducted on the NeoConnect™ Enteral Syringe:

- Finished Device
  - Risk Analysis including design, user and process FMEA (Failure Modes and Effects Analysis) in accordance with EN ISO 14971:2012
  - Human Factors and Usability Validation
  - Biocompatibility
    - ISO 10993-5: Cytotoxicity
    - ISO 10993-10: Irritation and sensitization
    - ISO 10993-11: Acute Toxicity
  - Chemical Testing
    - Extractables and Leachables
  - Finished Device Verification Testing
    - Critical Dimension verification
    - Ink Adhesion
    - ISO 7886
      - Capacity Tolerance
      - Graduated Scale
      - Piston Fit in Barrel
      - Air and Liquid Leakage Testing
- Syringe Tip (ENFit connector)
  - Enteral Connector Misconnection Assessment
  - ENFit Connector Risk Management Report (including misconnections FMEA)
  - Human Factors Validation Study
  - Dimensional verification
  - Liquid Leakage Testing
  - Stress Cracking
  - Resistance to separation from axial load
  - Resistance to separation form unscrewing
  - Resistance to overriding
  - Disconnection by unscrewing

VIII. CONCLUSIONS

The NeoMed NeoConnect™ Enteral Syringes are substantially equivalent to the NeoMed Oral / Enteral Syringe (K122373).